Department of Defense
Department of the Navy
Human Research Protection Program

Directions for Submitting a Joint Research Review Agreement

When is a Joint Research Review Agreement needed?

1. Use a Joint Research Review Agreement (JRRA) when federal institutions engaged* in DoD-DON-supported research with human subjects:

a. collaborate and jointly perform research with other federal institutions, each institution relying on its own IRB for review, approval, and oversight. Both institutions are equally responsible for the IRB review and for monitoring and overseeing the performance of the research at their respective institutions.

b. collaborate and jointly perform research with other federal institutions and the institutions agree to rely on IRB(s) of a federal institution(s). One institution is responsible for the IRB review while both institutions are equally responsible for monitoring and overseeing the performance of the research at their respective institutions.

c. agree that one federal institution, as a single performance site, may rely on IRB(s) of other federal institutions to review, approve, and oversee research. The role and responsibilities of the federal institution with the reviewing IRB is limited to IRB review and oversight. The performing institution is responsible for monitoring and overseeing the performance of the research.

* *An institution becomes "engaged" in human subjects research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes.* [32 CFR 219.102(d),(f) and OHRP policy January 1999]

2. Use a JRRA for one specific research protocol, a designated group of research protocols, or for all research protocols at the institution, whether or not the research is conducted jointly or by only one of the institutions.

3. Initiate a JRRA any time federal institutions choose to conduct joint research and/or rely on IRB(s) of other institutions.

4. Use a JRRA between federal and *non-federal* institutions, if appropriate. In these situations, the DON institution must submit the proposed JRRA to the DON HRPP for review and approval prior to finalizing and executing the agreement.

5. The JRRA **does not replace**:

a. The Cooperative Research and Development Agreement (CRADA). The human research protections elements of the JRRA may be incorporated, as appropriate, into CRADAs and eliminate the need for a JRRA.

b. Documents for transferring funds or materiel. These documents are needed in addition to the JRRA.

Step-by-Step Directions

1. Fill in the required information:

a. **Header:** Insert the institutions' names in the header.

b. **Paragraph 1. Names of Institutions:** Fill in the information for institutions that are part of the JRRA. There can be more than two institutions. If an institution also holds a Federalwide Assurance (FWA) and registered IRBs, include that information. If an institution does not hold a FWA with registered IRBs, delete the lines referring to FWA and IRB registration. The DON HRPP Directory contains this information for all DoD Navy institutions with assurances. The OHRP website lists the FWA number for institutions with FWAs. See http://ohrp.cit.nih.gov/search/asearch.asp#ASUR

c. **Paragraph 2. Research Covered by this Agreement:** Use this section to describe the research covered by this agreement.

1) One specific research protocol, whether or not the research is conducted jointly or by only one of the institutions.

2) Designated group of research protocols, whether or not the research is conducted jointly or by only one of the institutions. Institutions may list research protocols in an enclosure to the JRRA and update the enclosure as needed. The list should include, at least, research protocol number, title, and principal investigator's name.

3) All research protocols at the institution, whether or not the research is conducted jointly or by only one of the institutions.

d. **Paragraph 3. Institutional Responsibility**: If the institutions are federal, there are no changes to this section.

e. **Paragraph 4. Review of Research by Institutional Review Boards (IRB):** Insert the name(s) of the institutions that will review the research described in the preceding paragraph.

See the chart at the end of these directions below for determining which items of paragraph 4a and 4b apply.

f. **Paragraph 5. Liability:**

1) If institutions are federal, use the first paragraph and delete the second paragraph.

2) If one institution is non-federal, use the second paragraph and delete the first paragraph.

g. **Paragraph 6. Effective Dates:**

1) For agreements that cover all research protocols, add a specific date approximately three (3) years later.

2) For agreements covering a specific research protocol(s), base the expiration on the expected duration of the research and review of final, completion report by the reviewing IRB as long as the time period does not exceed three years.

h. **Paragraph 7. Amendments and Termination**: No changes necessary.

i. **Signature Blocks:** Insert Institution Officials' name, title, and institution name. Leave date blank for signer to fill in. All signatures and dates must be original, handwritten on hard copy or signed documents that have been scanned and submitted electronically.

2. Submit the JRRA to DON HRPP:

a. Institutions may submit a DRAFT JRRA to DON HRPP for pre-review and feedback prior to submitting the fully signed agreement.

b. Institutions using a standard JRRA may negotiate and submit the finalized agreement to the DON HRPP for headquarters-level administrative review. Submit JRRAs promptly after they are negotiated and executed.

c. Institutions electing to use agreements other than the JRRA must submit their proposed alternative to the DON HRPP prior to finalizing the agreement.

d. Institutions entering into agreements in which they will rely on IRB(s) of *non-federal* institutions must submit the JRRA to the DON HRPP prior to finalizing the agreement.

e. Send to:

Department of the Navy
Human Research Protection Program
Bureau of Medicine and Surgery (Code M00R)
2300 E Street NW
Washington, D.C. 20372-5300

FAX: 202-762-0976
Email: humanresearch@us.med.navy.mil

Chart for Determining which Items of paragraph 4a and 4b Apply

JRRA Item	Institution with IRB **and** performing research	Institution with IRB **and** performing research	Institution with IRB **not** performing research	Institution performing research, relying on other IRB	Institution with IRB **and** performing research	Institution performing research, relying on other IRB
4a(1)	X		X		X	
4a(2)	X		X		X	
4a(3)	X		X		X	
4a(4)	X		X		X	
4a(5)	Change to "Verify Inst & IRB approval."		X		Change to "Verify Inst & IRB approval."	
4a(6)	Not applicable		X		Not applicable	
4a(7)(a)	X		Delete		X	
4a(7)(b)	X		Delete		X	
4a(7)(c)	Tailor to specific research protocol or all research, etc.		Delete		Tailor to specific research protocol or all research, etc.	
4a(8)	X		X		X	
4a(9)	X		Delete		X	
4b(1)		X		X		X
4b(2)		X		X		X
4b(3)		X – Select "conduct or verify"		X – Select "conduct or verify"		X – Select "conduct or verify"
4b(4)		X – Select "Provide initial."		X		X
4b(5)(a)		X		X		X
4b(5)(b)		X		X		X
4b(5)(c)		X – Tailor to specific research protocol or all research, etc.		X – Tailor to specific research protocol or all research etc.		X – Tailor to specific research protocol or all research, etc.
4b(6)		X		X		X
4b(7)		X		X		X